Medical Device Recalls

Class 2 Recall
Medtronic Advanced Energy Aquamantys3 Pump Generator

Date Posted: January 31, 2014
Recall Status: Open
Recall Number: Z-0905-2014
Product Classification: Electrosurgical, Cutting & Coagulation & Accessories
Product: Medtronic Advanced Energy Aquamantys3 Pump Generator; Product Catalog Number: 10-1357 (Generator assembly), 40-404-1 (as shipped, including accessories) The Aquamantys3 System combines radio frequency (RF) energy and saline to reduce blood loss during and after surgical procedures. This patented Transcutaneous technology has been shown to reduce transfusion rates and may also reduce the need for other blood management procedures.
Code Information: lowest serial number is GN001141; the highest is GN001704 (non-consecutive)
Recalling Firm/Manufacturer: Medtronic Advanced Energy, LLC
180 International Dr
Portsmouth, New Hampshire 03801-6837
Manufacturer Reason for Recall: The internal protection circuitry on the electrosurgical output that prevents a patient from exposure to DC voltage when the device is activated is being compromised during normal use.
Action: Medtronic sent an Urgent Product Removal Notification on November 12, 2013, via Next Day FEDEX. The communication advises users to immediately stop using the affected AQM3 electrosurgical generators and quarantine them until they can be returned to Medtronic Advanced Energy. Medtronic field personnel will collect them in order to remove them from service and return them to Medtronic Advanced Energy. Customers with questions were instructed to contact Customer Service at 888-777-9400. For questions regarding this recall call 888-777-9400.
Quantity in Commerce: 242 devices
Distribution: Nationwide Distribution including CA, MO, PA, NJ, NY, OH, VA, TX, NC, DE, KS, TN, LA, IL, MI, SC, WI, and FL.
Total Product Life Cycle: TPLC Device Report

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §5225

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdhr/devicesatfda/index.cfm
7. /scripts/cdhr/cfdocs/cfPMN/pmnm.cfm
8. /scripts/cdhr/cfdocs/cfRL/rl.cfm
9. /scripts/cdhr/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdhr/cfdocs/cfRES/res.cfm
11. /scripts/cdhr/cfdocs/cfPMA/pma.cfm
12. /scripts/cdhr/cfdocs/cfPCD/classification.cfm
13. /scripts/cdhr/cfdocs/cfSTANDARDS/search.cfm
14. /scripts/cdhr/cfdocs/cfTPLC/inspect.cfm
15. /scripts/cdhr/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdhr/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdhr/cfdocs/cfAssem/Assembler.cfm
18. /scripts/cdhr/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdhr/cfdocs/cfCfia/Search.cfm